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PATENT -- FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In Re: Application of)
PETER NASH ET AL)
Serial No.: 10/038,260)
Filed: January 7, 2002) Group Art Unit 1644
For: IMMUNOGEN ADHERENCE INHIBITOR) Exr. P. Huynh
AND METHOD OF MAKING AND)
USING SAME)
Case Docket No.: C150.12.3C)

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22131-1450

Sir:

Enclosed are the original and three (3) copies of Appellants' Brief under 37 CFR 41.37.

The brief filing fee has been paid with the original Brief.

Appellants are individual inventors and claim small entity status.

Respectfully submitted,

PETER NASH ET AL

By Richard John Bartz
Richard John Bartz
Registration No. 40,500
Southdale Office Centre
6750 France Avenue South, Suite 350
Edina, MN 55435-1983
(952) 920-3959

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RICHARD JOHN BARTZ
Name of applicant, assignee, or Registered Rep.

R. John Bartz
Signature

JULY 17, 2006
Date of Signature



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APPELLANTS' BRIEF UNDER 37 CFR 41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is in support of an appeal to the Board of Appeals from the final rejection dated February 13, 2004 of Claims 1, 3 and 5 to 38. Copies of these claims are attached Claims Appendix.

1. REAL PARTY IN INTEREST

The real party in interest is Camas Incorporated, a Minnesota corporation having a place of business at 260 Derrynane Street, Le Center, Minnesota 56057, assignee of the invention and application.

2. RELATED APPEALS AND INTERFERENCES

U.S. Application Serial No. 09/616,843, parent application, and related Application Serial No. 10/025,567 are pending before the Board of Appeals and Interferences.

3. STATUS OF CLAIMS

Claims 1, 3 and 5 to 38 are pending in the application. This appeal concerns Claims 1, 3 and 5 to 38.

Claims 1, 3 and 5 to 38 have been rejected under 35 USC 112.

Claims 5 and 32 to 38 have been rejected under 36 USC 112, New Matter.

Claims 1, 3 and 5 to 38 have been rejected under 35 USC 103(a).

No claims have been allowed.

4. STATUS OF AMENDMENTS

Amendments 37 CFR 1.116 was filed August 30, 2004 and February 2, 2005 have been entered.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed invention is directed to a method for the production of a microbial adherence inhibitor for administration to food host animals to inhibit the attachment or adherence of colony-forming immunogens or haptens in the rumen and intestinal tract the host food animals. The method promotes the growth of food animals by improving feed conversion rates by decreasing the waste of dietary protein caused by the presence of certain colony-forming protein-wasting organisms in food animals.

Common bacterial immunogens which cause dramatic decreases in an animal's ability to utilize dietary protein include but are not limited to *Peptostreptococcus anaerobius*, *Clostridium aminophilum*, and *Clostridium sticklandii*. These organisms have been collectively primarily responsible for wasting up to 25 percent of the protein in cattle diets. This is a loss of as much as \$25 billion annually to cattle producers and is especially apparent in grazing animals which are often deficient in protein, even though their protein intake appears to be adequate. As the host animals consume protein in the diet, these deleterious organisms wastefully degrade the protein to ammonia which is converted to urea by the liver

and kidneys and thus lost to the host animals when excreted as urine. These deleterious organisms also compete with beneficial organisms which the host animals need for the efficient utilization of ammonia.

The young of chickens receive passive antibody protection through the store of antibodies placed in the eggs in which they develop from the embryonic stage. Chickens, in particular, have the ability to "load up" their eggs as they are formed, with a very large supply of antibodies concentrated many fold over that which is present in the serum of the hen. In addition, chicken antibodies are much more stable and resistant to inactivation through digestion than mammalian antibodies, especially under adverse conditions. Once immunized the hen layers the unique IgY types immunoglobulins in the yolk while depositing chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. Furthermore, the large quantities of antibodies which are placed in eggs are much more exclusively those specific for the antigens to which the hen has most recently been exposed to and challenged by. This all results in the eggs of chickens being a most ideal source for large quantities of economically produced, highly specific and stable antibodies.

The method for the production of microbial adherence inhibitor for administration to host food animals to inhibit the adherence of colony-forming immunogens in the rumen and/or intestinal tracts of the food animals comprises first inoculating female chickens, in or about to reach their egg laying age, with the particular target immunogen. Then, after a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, the eggs laid by the birds are harvested. The total antibody-containing contents of the eggs are separated from the shells and dried. The dried separated egg antibody adherence inhibiting material may be stored or shipped for use when needed. The dried egg contents incorporating the antibody specific to the targeted immunogen is administered to the food animals by distributing the antibody material substantially uniformly throughout an animal feed and then supplying the resulting antibody-containing animal feed to the food animals. The antibody-containing

animal feed is supplied to food animals during the normal finishing schedule prior to slaughter. The substantial prevention of colonization of the targeted organism in the rumen or intestinal tract of the animal will ultimately permit elimination of the organism from the animal. This repression of colonization and elimination of the subject organisms will permit a significant decrease in wasteful degradation of the dietary protein fed to food production animals. In addition, the resulting decrease in competition to the non-ammonia producing organisms will further enhance the most efficient utilization of feed by the host.

The specification including the claims define methods for the production of a microbial adherence inhibitor that promotes the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The control of growth of the colony forming wasting immunogen in the animal boosts feed efficiency and promotes growth of the animal. *Specification, page 7, lines 3 to 17.* The targeted protein wasting immunogen is from a class consisting of *P.anaerobius*, *C.sticklandii* and *C.aminophilium*. These immunogens are described in Examples 7, 8 and 9 on pages 16-18 of the specification. Examples 17, 18 and 19 relate to these immunogens. *Specification, pages 21-22.* Organisms that colonize in the rumen and digestive tract of host animals must possess the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 8, lines 19-20.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, lines 1-3.* Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification, page 10, lines 2-4.* The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 10, lines 4-5.*

The organism inhibitor is the colonizing microorganism adhesion inhibitor that is chicken antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 12, lines 11-13*. The albumin IgM and IgA immunoglobulins bind in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. Appellants have discovered that egg IgY immunoglobulins bind to protein-wasting immunogens thereby inhibiting adherence of the immunogens in the intestinal tracts of animals. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted colony-forming immunogen in the digestive tract of the animal.

An alternate embodiment of the method includes the coating of carrier material with the whole egg yolk and albumin. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard animal feeds. *Example 21, page 23*. The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The yolk and albumin immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby preventing adherence of the protein-wasting immunogen in the intestinal tract of the animal. The coated carrier material increases the duration of the effectiveness of the IgY, IgM and IgA immunoglobulins.

A further embodiment of the method includes the use of coating the mixed whole egg yolk and albumin on dry carrier material to dry the egg yolk and albumin. A separate drying process is not used prior to coating of the carrier material with the egg yolk and albumin. The elimination of a separate drying step increases the effectiveness of the immunoglobulins in inhibiting adherence immunogens in the intestinal tracts of animals.

CLAIM 1

Claim 1 defines a method for the production of a microbial adherence inhibitor for promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of colony forming protein wasting immunogen in the rumen or intestinal tracts of the animals. The control of growth of the colony forming wasting immunogen in the animal boosts feed efficiency and promotes growth of the animal. The particular target protein wasting immunogen is a colony forming protein wasting immunogen. Examples of this immunogen are from a class consisting of *E. coli*, *Listeria*, *Salmonella*, *Campylobacter*, *P. anaerobius*, *C. sticklandii* and *C. aminophilium*. These immunogens are described on pages 16-18 of the specification, ¶¶ 0025, 0040, 0041 and 0042. Organisms that colonize in the rumen and digestive tract of a host animal must possess the capability of sticking or adhering to the rumen or intestinal tract surface in order to multiply and grow. *Specification, page 8, ¶ 0027, lines 1, 2.* The organism inhibitor of the invention interferes with adherence in a highly specific manner and on a cumulative basis prevent the targeted organism from multiplying, growing and colonizing. *Specification, page 9, ¶ 0027, lines 6-8.* Immunized hens layer unique IgY type immunoglobulins in the yolk of the egg and deposit IgM and IgA immunoglobulins in the albumin. *Specification, page 10, ¶ 0028, lines 10-12.* The albumin containing the IgM and IgA immunoglobulins helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification, page 10, ¶ 0028, lines 12-13.* The organism inhibitor is the colonizing

microorganism adhesion inhibitor that is chicken antibody, IgY immunoglobulins, which can very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Specification, page 12, ¶ 0032, lines 4-6.* As defined in Claim 1 the entire contents of the eggs when administered to food animals with animal feed promote the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a colony-forming immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the colony-forming immunogen. The binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the colony-forming immunogen to adhere to the rumen or intestinal tracts of the food animals. The albumin IgM and IgA immunoglobulins bind in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animals. Albumin is a protein that protects the activity of the IgY type immunoglobulins thereby increasing their active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animals.

CLAIM 3

Claim 3 depends on Claim 1. This claim defines the targeted colony-forming immunogen from the class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilum*. *Specification, page 7, ¶ 0025, lines 1-3; page 16, Example 7; page 17, ¶¶ 0041 and 0042, Examples 8 and 9.*

CLAIM 5

Claim 5 defines a method for the production of a microbial adherence inhibitor for

administration to a living being to inhibit the adherence of a colony-forming immunogen in the digestive tract of the living being. The colony-forming immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. *Specification*, page 7, ¶ 0025, lines 1-3; page 17, ¶¶ 0041 and 0042. The entire contents of said eggs when administered to the living being inhibiting the adherence of the colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins. *Specification*, page 12, ¶ 0032, lines 1-6. These binding characteristics are also defined in Claim 1.

CLAIM 6

Claim 6 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of food animals. Antibody to the targeted colony-forming immunogen in the bird eggs include IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs. A dry food carrier material is coated with the entire contents of the eggs. The dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibits the adherence of colony-forming immunogen in the digestive tract of the food animals by binding the IgY immunoglobulins to the colony-forming immunogen. The binding of the IgY immunoglobulins to the colony-forming immunogen is assisted by the IgM and IgA immunoglobulins. The coated carrier material increases the duration of the effectiveness of the IgY immunoglobulins and facilitates mixing with standard animal feeds. The dry carrier material coated with the egg contents removes moisture from the egg contents thereby eliminating a separate drying process in the preparation of the microbial adherence inhibitor. The coating of carrier material and drying of the eggs is

described in the specification, page 23, ¶ 0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 7

Claim 7 depends upon Claim 6. The claim further defines the dry feed carrier material from a group including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

CLAIM 8

Claim 8 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of food animals. The immunogen is P antigen from *P. anaerobius*. *Specification, page 16, ¶0040*. This method includes the method for the production of a microbial adherence inhibitor defined in Claim 1.

CLAIMS 9 AND 10

Claims 9 and 10 depend on Claim 8. These claims further define the drying process of the entire contents of the eggs. A dry carrier material is coated with the eggs to dry the eggs as described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 11

Claim 11 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of food animals. The immunogen is CS antigen from *C. sticklandii*. *Specification, page 17, ¶0041*. This method includes the method for the production of a microbial adherence inhibitor defined in Claim 1.

CLAIMS 12 AND 13

Claims 12 and 13 depend on Claim 11. These claims further define the drying process of the entire contents of the eggs. A dry carrier material is coated with the eggs to dry the eggs as

described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 14

Claim 14 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of food animals. The immunogen is CA antigen from *C. aminophilum*. *Specification, page 17, ¶0042*. This method includes the method for the production of a microbial adherence inhibitor defined in Claim 1.

CLAIMS 15 AND 16

Claims 15 and 16 depend on Claim 14. These claims further define the drying process of the entire contents of the eggs. A dry carrier material is coated with the eggs to dry the eggs as described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 17

Claim 17 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of food animals. The immunogen is *E. coli* antigen from *E. coli*. *Specification, page 7, ¶0025 and page 13, ¶0035*. This method includes the method for the production of a microbial adherence inhibitor defined in Claim 1.

CLAIMS 18 AND 19

Claims 18 and 19 depend on Claim 17. These claims further define the drying process of the entire contents of the eggs. A dry carrier material is coated with the eggs to dry the eggs as described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 20

Claim 20 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the

rumen or intestinal tracts of food animals. The immunogen is *Listeria* antigen from *Listeria*. *Specification*, page 7, ¶0025. This method includes the method for the production of a microbial adherence inhibitor defined in Claim 1.

CLAIMS 21 AND 22

Claims 21 and 22 depend on Claim 20. These claims further define the drying process of the entire contents of the eggs. A dry carrier material is coated with the eggs to dry the eggs as described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 23

Claim 23 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of food animals. The immunogen is *Salmonella* antigen from *Salmonella*. *Specification*, page 7, ¶0025. This method includes the method for the production of a microbial adherence inhibitor defined in Claim 1.

CLAIMS 24 AND 25

Claims 24 and 25 depend on Claim 23. These claims further define the drying process of the entire contents of the eggs. A dry carrier material is coated with the eggs to dry the eggs as described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 26

Claim 26 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of food animals. The immunogen is *Campylobacter* antigen from *Campylobacter*. *Specification*, page 7, ¶0025. This method includes the method for the production of a microbial adherence inhibitor defined in Claim 1.

CLAIMS 27 AND 28

Claims 27 and 28 depend on Claim 26. These claims further define the drying process of the entire contents of the eggs. A dry carrier material is coated with the eggs to dry the eggs as described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 29

Claim 29 defines a method for the production of a microbial inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen or bacteria in the rumen or intestinal tracts of food animals. The method includes providing a dry carrier material and coating the dry carrier material with the entire contents of the eggs to dry the eggs. The dry carrier material coated with the eggs removes moisture from the eggs thereby eliminating a separate drying process. The coating material and drying of the eggs is described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIMS 30 AND 31

Claims 30 and 31 depend on Claim 29. These claims further define the carrier material and class of immunogens or bacteria.

CLAIM 32

Claim 32 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the ability of an immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply. The protein-wasting immunogen is P antigen from *P. anaerobius*. The method includes providing a dry carrier material and coating the dry carrier material with the entire contents of the eggs to dry the eggs. The dry carrier material removes moisture from the eggs thereby eliminating a separate drying process. The coating material and drying of the eggs is described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 34

Claim 34 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the ability of an immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply. The protein-wasting immunogen is CS antigen from *C. sticklandii*. The method includes providing a dry carrier material and coating the dry carrier material with the entire contents of the eggs to dry the eggs. The dry carrier material removes moisture from the eggs thereby eliminating a separate drying process. The coating material and drying of the eggs is described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 36

Claim 36 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the ability of an immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply. The protein-wasting immunogen is CA antigen from *C. aminophilum*. The method includes providing a dry carrier material and coating the dry carrier material with the entire contents of the eggs to dry the eggs. The dry carrier material removes moisture from the eggs thereby eliminating a separate drying process. The coating material and drying of the eggs is described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

CLAIM 38

Claim 38 defines a method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the ability of an immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply. The protein-wasting immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The method includes providing a dry carrier material and coating the dry carrier

material with the entire contents of the eggs to dry the eggs. The dry carrier material removes moisture from the eggs thereby eliminating a separate drying process. The coating material and drying of the eggs is described in the specification, page 23, ¶0056, lines 1-10 and page 24, ¶0057, lines 1-8.

In summary, the claims fall into three groups. The claims of Groups I, II and III do not stand or fall together. Each group of claims define a distinct and novel method for the production of a microbial adherence inhibitor for promoting the growth of food animals.

Group I comprises Claims 1, 3, 5, 8, 17, 20, 23 and 26. These claims define a method for the production of a microbial adherence inhibitor that promotes the growth of food animals by decreasing the waste of dietary protein caused by the presence of targeted colony-forming protein-wasting immunogens. The protein-wasting immunogens are from the class consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The method includes drying of the entire contents of eggs having yolks with IgY and albumin IgM and IgA immunogens. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens.

Group II comprises Claims 9-10, 12-13, 15-16, 18-19, 21-22, 24-25 and 27-28. These claims include the subject matter of parent Claims 8, 11 14 and 17 and the process of drying the entire contents of the eggs having yolk IgY and albumin IgM and IgA immunoglobulins by coating dry carrier material with the entire contents of the eggs. The dry carrier material is from a group of materials including

soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beat pulp. The coated carrier material increases the duration of the effectiveness of the IgY immunoglobulins and facilitates mixing with standard animal feeds.

Group III comprises Claims 6-7 and 29-38. These claims define a microbial adherence inhibitor produced by the method of promoting the growth of food animals by decreasing the waste dietary protein caused by the presence of colony-forming protein-wasting immunogens in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals to reduce the ability of the immunogen to multiply, the immunogens include P antigen from *P. anaerobius*, CS antigen from *C. sticklandii* and CA antigen from *C. aminophilum*. The method includes providing a dry carrier material, coating the dry carrier material with the antibody and albumin of the harvested eggs. The carrier material coated with the antibody yolk and albumin is distributed substantially uniform in animal feed. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens. The method does not include a separate step of drying the antibody yolk and albumin as required by the method of Group II Claims 9-10, 12-13, 15-16, 18-19, 21-22, 24-25 and 27-28.

6. GROUNDS OF REJECTION TO BE REVIEW ON APPEAL

A. Claims 1, 3 and 5-38 are rejected under 35 USC 112, first paragraph, because the specification while being enabling only for a method for the production of a microbial adherence inhibitor in the form of IgY for administration to food animals to inhibit the adherence of targeted colony-forming bacteria selected from the group consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* in the rumen or intestinal tracts of the food animals does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

B. Claims 1, 3 and 5-38 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

C. Claims 5 and 32-38 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

D. Claims 1, 3, 5, 8, 11, 14 and 17 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*); or *Yokoyama et al (Infection and Immunity*, 60(3): 998-1007, March 1992), each in view of *Kaspers et al (Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,741,489 (*Pimental*), *Krause et al (Appl Environ Microbiol*, 62(3): 815-821, 1996) and *Trinchieri et al (Urol Res*, 18(5): 305-308, 1990).

E. Claims 5, 20, 23 and 26 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) or *Yokoyama et al (Infection and Immunity*, 60(3): 998-1007, March 1992),

each in view of *Kaspers et al* (*Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,741,489 (*Pimental*), *Krause et al* (*Appl Environ Microbiol*, 62(3): 815-821, 1996) and *Trinchieri et al* (*Urol Res*, 18(5): 305-308, 1990) as applied to Claims 1, 3, 5, 8, 11, 14 and 17 and further in view of U.S. Patent No. 4,748,018 (*Stolle et al*), and *Sugita-Konishi et al* (*Biosci Biotechnol Biochem*, 60(5): 886-888, May 1996).

F. Claims 6, 7, 9, 10, 12, 13, 15-16, 18, 19 and 29-38 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) or *Yokoyama et al* (*Infection and Immunity*, 60(3): 998-1007, March 1992), each in view of *Kaspers et al* (*Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,741,489 (*Pimental*), *Krause et al* (*Appl Environ Microbiol*, 62(3): 815-821, 1996) and *Trinchieri et al* (*Urol Res*, 18(5): 305-308, 1990) as applied to Claims 1, 3, 5, 8, 11, 14 and 17 and further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), and U.S. Patent No. 4,166,867 (*Betz et al*).

G. Claims 20-28 and 38 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) or *Yokoyama et al* (*Infection and Immunity*, 60(3): 998-1007, March 1992) each in view of *Kaspers et al* (*Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,471,489 (*Pimental*), *Trinchieri et al* (*Urol Res*, 18(5): 305-308, 1990), U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 4,166,867 (*Betz et al*), U.S. Patent No. 4,748,108 (*Stolle et al*), and *Sugita-Konishi et al* (*Biosci Biotechnol Biochem*, 60(5): 886-888 (May 1996)).

H. Claims 1, 3 and 5-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-16, 19-24, 27-32 of co-pending Application Serial No. 09/616,843.

I. Claims 5 and 17-28 are provisionally rejected under the judicially created doctrine of obviousness double patenting as being unpatentable over Claims 1-18 of co-pending

7. **ARGUMENT**

A. Claims 1, 3 and 5-38 are rejected under 35 USC 112, first paragraph, because the specification while being enabling only for a method for the production of a microbial adherence inhibitor in the form of IgY for administration to food animals to inhibit the adherence of targeted colony-forming bacteria selected from the group consisting of *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* in the rumen or intestinal tracts of the food animals does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification of the application complies with the requirements of 35 USC 112.

Under 35 USC 112 ¶ 1 "[t]he specification shall contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The specification clearly discloses Appellants' method for the production of a microbial adherence inhibitor promoting the growth of living beings including food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of food animals and living beings.

The Examiner has construed the requirements of 35 USC 112 to include any person skilled in the art to make and use the invention commensurate in scope with the claims. *Office action 2/13/2004, page 2, lines 24-26*. This is not the requirement of 35 USC 112 ¶ 1. It is the specification, according to 35 USC 112 ¶ 1, that contains the written description to enable a person skilled in the art to make and use the same.

The specification describes the methods of Selection of Egg laying avian hens, pages 12-13; Preparation of Stock Culture, page 12; Preparation of H antigens for Immunogens, pages 13-

14; Preparation of O antigens for immunogens, pages 14-15; Preparation of A antigen for immunogen, pages 15-16; Preparation of P antigen for immunogen, pages 16-17; Preparation of CA antigen for immunogen, pages 17-18; Analysis of individual eggs and serum over time, page 19; Immunization of chickens with immunogens, page 20-22; and Feeding of Cattle, pages 27-28. The specification contains a detailed description and best mode of Appellants' process of promoting the growth of food animals, such as cattle, by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of the animals to reduce the ability of the immunogen to multiply. This description enables a person skilled in the art to make and use the subject method for the production of a microbial adherence inhibitor.

Appellants have provided a representative number of species of colony-forming protein-wasting immunogens to describe the genus identified by the terms target colony-forming immunogens. These immunogens are well known protein-wasting immunogens. The species of immunogens are identified as from a class consisting of: *P. anaerobius*, *C. sticklandii*, *C. aminophilum*, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. This class is sufficient to identify a genus of like immunogens to a person skilled in the art. One skilled in the art would be aware of the bacterial antigens noted by *Stolle et al '018* in column 5, lines 5-35. Claims 1, 3, 5-38 particularly point out and distinctly claim the subject matter of Appellants' method for the production of a microbial adherence inhibitor as described in the specification.

Appellants request that this rejection of Claims 1, 3 and 5-38 be reversed.

B. Claims 1, 3 and 5-38 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attach themselves to their hosts. *Page 12, lines 11-13*. The particular language is the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins." This process is supported by the disclosure that hen layers the unique IgY types immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Specification page 10, lines 4-5*. The whole egg preparation includes the IgY immunoglobulins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the finding of IgY immunogens to the protein-wasting immunogens as more IgY immunogens are available to find to the protein-wasting immunogens.

The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The IgM and IgA immunoglobulins have di-sulfide bonds that retain molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type

immunoglobulins thereby increasing their active life in the intestinal tract. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tract of the animal.

The specification supports the method for production of a microbial adherence inhibitor defined in Claims 1, 3 and 5-38.

Appellants request that this rejection of Claims 1, 3 and 5-38 be reversed.

C. Claims 5 and 32-38 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The Examiner states that the terms “living being” represents a departure from the specification and claims as originally filed.

Claims 32-38 has been amended to change “living being” to --food animals-- in the amendment entered February 2, 2005. Accordingly, this rejection does not apply to claims 32-38.

Claim 5 defines a method for the production of a microbial adherence inhibitor for administration to a living being to inhibit the adherence of colony-forming immunogen from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

The specification describes the microbial adherence inhibitor used for food animals and hosts to inhibit adherence of colony-forming immunogens in the rumen and intestinal tracts. The hosts and animals are living beings as they are alive and exist. The terms living being is not indefinite. The term host is included in the specification, page 8, ¶0027, lines 1-2 and page 29, ¶0066, lines 1-2. The terms “living beings” as the live hosts in Claim 5 is not new matter to this claim.

The rejection of Claim 5 should be reversed.

D. Claims 1, 3, 5, 8, 11, 14 and 17 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*); or *Yokoyama et al* (*Infection and Immunity*, 60(3): 998-1007, March 1992), each in view of *Kaspers et al* (*Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,741,489 (*Pimental*), *Krause et al* (*Appl Environ Microbiol*, 62(3): 815-821, 1996) and *Trinchieri et al* (*Urol Res*, 18(5): 305-308, 1990).

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levensgood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

The Federal Circuit has also made it clear that the showing of a motivation to combine two or more references must be "clear and particular". See for example *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 202 F.3d 1340 (Fed. Cir. 2000), where the Federal Circuit stated:

When an obviousness determination is based on multiple references, there must be a showing of some "teaching, suggestion, or reason" to combine references. [Citation omitted].

Although a reference need not expressly teach that the disclosure contained therein should be combined with another, [citation omitted] the showing of combinability, in whatever form, must nevertheless be "clear and particular."

As the Federal Circuit also stated:

"The factual inquiry whether to combine references must be thorough and searching" *Id.* It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.

In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002).

The Examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. This burden can only be shown by some objective teaching in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 1 and 5 define a method for the production of a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of living beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

Claim 3 depends upon Claim 1. Claim 3 further defines the targeted colony-forming immunogen as being from the class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilium*.

Claims 8, 11, 14 and 17 define a method for the production of a microbial adherence inhibitor for promoting growth of food animals by decreasing waste of dietary protein caused by protein-wasting immunogen. The entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins are administered to the animals to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. The protein-wasting immunogens are identified as P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, CA antigen from *C. aminophilum* and *E. coli* antigen from *E. coli*.

Tokoro '895 discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, the albumin and the yolks of eggs. This method is related to the use of raw eggs by cattle herders to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro '895* is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in *Tokoro '895* of an IgY immunoglobulin that binds to a colony-forming immunogen. The antibody containing substance also is used as a nutrition supplement, and as an additive to food for animals. *Tokoro '895* does not provide a teaching of a method for the production of a microbial adherence inhibitor produced by the method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P. anaerobius*, CS antigen from *C. sticklandii*, CA antigen from *C. aminophilum*, and *E. coli* antigen from *E. coli* to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability

of the immunogens to multiply.

The *Kaspers et al* publication discloses the transfer of maternal antibodies into the egg of a chicken and subsequent transport thereof into a developing embryo. There is no disclosure in the *Kaspers et al* publication of IgY, IgM and IgA immunoglobulins whereby the IgY immunoglobulins bind to colony-forming or protein-wasting immunogens with the binding process being assisted by the IgM and IgA immunoglobulins thereby inhibiting the colony-forming or protein-wasting immunogens from adhering to the intestinal tracts of animals.

Pimental '489 discloses a method for increasing feed conversion efficiency in mammals with a diet containing an antibody produced using the enzyme urease as the antigen. *Pimental '489* states that chicken antibodies are generally known to protect the recipient against bacterial infections. No antibody has been shown to increase feed conversion efficient. *Col. 2, lines 59-63. Pimental '489* is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching in *Pimental '489* of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

Krause et al does not disclose or suggest that IgY immunoglobulins bind to protein-wasting immunogens and that IgM and IgA immunoglobulins assist and help the binding process.

Krause et al discloses that amino acid degradation in the rumen of animals is nutritionally wasteful and produces more ammonia than the bacteria in the rumen can utilize. The excess ammonia is converted by the animal into urea and discharged into the environment as environmental pollution. The feed additive monensin decreases ammonia accumulation in the rumen. *Krause et al* discovered that monensin inhibited growth of *P.anaerobius* and

C.sticklandii in the rumen of an animal but did not inhibit *C.aminophilum*. The result was the reduction in the amount of ammonia in the rumen and reduction of environmental pollution.

There is no teaching that monensin prevents adherence of a targeted immunogen in the intestinal tract of an animal thereby inhibiting its colony growth. Monensin does not promote the growth of food animals by preventing targeted immunogens from adhering to the intestinal tract of an animal. U.S. Patent Nos. 3,501,568 and 3,794,732 are directed to the use of monensin for promoting growth and feed efficiency of food animals. Monensin can be toxic to some animals. Feed intake of the animals is reduced as monensin cannot be added to molasses. *Specification, page 4, lines 8-14.*

The *Trinchieri et al* publication discloses urinary secretory immunoglobulins A used to inhibit bacterial adherence in human urinary tracts. *Trinchieri et al* do not disclose or suggest a method for promoting growth of food animals by binding IgY immunoglobulins to colony-forming immunogens assisted by IgM immunoglobulins and IgA immunoglobulins to inhibit the colony-forming immunogens from adhering to the intestinal tracts of the animals.

The *Yokoyama et al* publication discloses isolation of antibodies from chicken egg yolk. Immunoglobulin G (IgG) egg yolk was diluted with distilled water and mixed with ethyl alcohol. The mixture was centrifuged. The supernatant which contained the IgG was purified. This process does not disclose or suggest Appellants' method for production of a microbial adherence inhibitor defined in Claims 1, 3, 5, 8, 11, 14 and 17. There is no disclosure in *Yokoyama et al* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and the binding process is assisted or helped by IgM and IgA immunoglobulins.

It is submitted that Appellants' method of making a microbial adherence inhibitor produced by the method of promoting the growth of food animals as defined in Claims 1, 3, 5, 8,

11, 14 and 17 is patentable in view of the individual and combined teachings of *Tokoro '895* or *Yokoyama et al* in view of *Kaspers et al*, *Pimental '489*, *Krause et al* and *Trinchieri et al*.

Further, there are no motivating directions or suggestions in these references that would impel one skilled in the art to produce the claimed method. There is no teaching of a method of promoting the growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

There are insufficient teachings of the above combined references and no evidence of a motivating force which would impel one skilled in the art to make and use the claimed method for the production of a microbial adherence inhibitor. The numerous rejections of the claims is evidence that one skilled in the art would not determine that it is obvious to use IgY, IgM and IgA immunoglobulins in the entire contents of eggs to bind the IgY immunoglobulins to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

Further, the Examiner has completely failed to show any motivation to combine his references, either the *Tokoro '895* reference with the *Kaspers et al* reference, the *Pimental '489* reference, the *Krause et al* reference and the *Trinchieri et al* reference, or the *Yokoyama et al* reference with the *Kaspers et al* reference, the *Pimental '489* reference, the *Krause et al* reference and the *Trinchieri et al* reference. There is certainly no "clear and particular" showing of motivation to combine.

Appellants request that this rejection be reversed.

E. Claims 5, 20, 23 and 26 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) or *Yokoyama et al* (*Infection and Immunity*, 60(3): 998-1007, March 1992), each in view of *Kaspers et al* (*Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,741,489 (*Pimental*), *Krause et al* (*Appl Environ Microbiol*, 62(3): 815-821, 1996) and *Trinchieri et al* (*Urol Res*, 18(5): 305-308, 1990) as applied to Claims 1, 3, 5, 8, 11, 14 and 17 and further in view of U.S. Patent No. 4,748,018 (*Stolle et al*), and *Sugita-Konishi et al* (*Biosci Biotechnol Biochem*, 60(5): 886-888, May 1996).

Appellants' analysis, *supra*, of the primary references, *Tokoro '895* and *Yokoyama et al* and secondary references, *Kaspers et al*, *Pimental '489*, *Krause et al* and *Trinchieri et al*, are applicable to this rejection.

Claim 5 defines a method of production of a microbial adherence inhibitor that inhibits the adherence of a targeted colony-forming immunogen in the intestinal tracts of live beings including animals. This is accomplished by using the entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins.

Claims 20, 23 and 26 define the method of making the inhibitor as including immunogens *Listeria* antigen from *Listeria*, *Salmonella* antigen from *Salmonella* and *Campylobacter* antigen from *Campylobacter*.

Stolle et al '018 discloses a method of passive immunization of mammals using avian egg yolk antibody against any of a variety of antigens using various methods of administration under various conditions and using various compositions incorporating the antibody, after first developing in the mammal a tolerance for the antibody. The *Stolle et al* method of passive

immunization of a mammal has two steps. First, the mammal is fed a material having a heterologus protein antibody obtained from the egg of a fowl immunized against an antigen until the mammal develops substantial tolerance to the antibody. Second, the mammal is administered an antibody obtained from a fowl immunized against the antigen. There is no disclosure in *Stolle et al '018* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of the protein-wasting immunogens to adhere to the intestinal tracts of animals. Furthermore, *Stolle et al '018* does not disclose or suggest to one skilled in the art that the binding process is assisted or helped by IgM and IgA immunoglobulins.

The *Sugita-Konishi et al* publication discloses IgY immunoglobulins from egg yolk from hens immunized with an infections pathogen is efficient in prevention of the disease caused by the pathogen. The IgY immunoglobulin was isolated from the egg yolk of hens immunized with 26 strains of bacteria. The investigation of the function of isolated IgY immunoglobulin was limited to three infectious bacterial strains. There is no disclosure in *Sugita-Konishi et al* of IgY, IgM and IgA immunoglobulins with IgY immunoglobulins binding to protein-wasting immunogens to inhibit the ability of protein-wasting immunogens to adhere to the intestinal tracts of animals and that the binding process is assisted or helped by IgM and IgA immunoglobulins.

Further, the Examiner has again failed to show any motivation to combine his references. There is no "clear and particular" showing of motivation to combine the numerous references based on objective evidence of record.

Appellants request that this rejection be reversed.

F. Claims 6, 7, 9, 10, 12, 13, 15-16, 18, 19 and 29-38 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) or *Yokoyama et al* (*Infection and Immunity*, 60(3): 998-1007, March 1992), each in view of *Kaspers et al* (*Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,741,489 (*Pimental*), *Krause et al* (*Appl Environ Microbiol*, 62(3): 815-821, 1996) and *Trinchieri et al* (*Urol Res*, 18(5): 305-308, 1990) as applied to Claims 1, 3, 5, 8, 11, 14 and 17 and further in view of U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), and U.S. Patent No. 4,166,867 (*Betz et al*).

Appellants' analysis, *supra*, concerning the primary references, *Tokoro '895* and *Yokoyama et al*, and secondary references, *Kaspers et al*, *Pimental '489*, *Krause et al* and *Trinchieri et al*, are applicable to this rejection.

Claims 6, 29, 32, 34, 36 and 38 define the method of making a microbial adherence inhibitor as including the step of providing a dry carrier material. The dry carrier material is coated with the separated entire contents of the harvested eggs. The dry carrier material coated with the entire contents of the eggs inhibits the adherence of colony-forming protein-wasting immunogens in the digestive tracts of animals by binding IgY immunoglobulins to the immunogens and assisting or helping the binding process with IgM and IgA immunoglobulins. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 23*. The feed mixed with the carrier material coated with entire contents of the eggs is supplied to the animals. The carrier material flows with the animal feed down the animals' digestive tracts exposing the IgY, IgM and IgM to colony-forming protein-wasting immunogens therein.

Claim 32 further defines the protein-wasting immunogens as being P antigen from *P. anaerobius*.

Claim 34 further defines the protein-wasting immunogens as being CS antigen from *C. sticklandii*.

Claim 36 further defines the protein-wasting immunogens as being CA antigen from *C. aminophilium*.

Claim 38 further defines the colony-forming immunogens as being from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

Claim 7 depends upon Claim 6, Claim 30 depends upon Claim 29, Claim 33 depends upon Claim 32 and Claim 35 depends upon Claim 34. Dependent Claims 7, 30, 33 and 35 more particularly define the carrier material as being from a group including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

Claim 31 depends on parent Claim 29 and further defines the targeted colony-forming immunogen as being from the class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilium*.

The separated entire contents of the harvested eggs are not dried before they are coated onto the dry carrier material. This avoids the reduction of the effectiveness of the IgY, IgM and IgA immunoglobulins caused by the process of drying the entire contents of the harvested eggs.

Claims 9-10, 12-13 and 15-16 are claims dependent upon parent Claims 8, 11 and 14. The parent Claims 8, 11 and 14 include the method of drying the entire contents of the eggs. The dependent Claims 9-10, 12-13 and 15-16 more particularly define the drying process. The drying of the separated entire contents of the eggs is achieved by coating the dry carrier material with the entire contents of the eggs. Parent Claims 8, 11 and 14 define the method of promoting growth of food animals by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens, P antigen from *P.anaerobius*, CS antigen from *C.sticklandii* and CA antigen from *C.aminophilium*, by inhibiting the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of immunogens to multiply. The method of Claims 9-10, 12-13 and 15-16 includes the step of

drying the separated entire contents of the harvested eggs with dry carrier material. The moisture of the entire harvested eggs on the dry carrier material is absorbed by the carrier material. This avoids the reduction of the effectiveness of IgY, IgM and IgA immunoglobulins caused by a separate drying process to dry the entire contents of the harvested eggs before coating the dry carrier material with said contents of the eggs.

Adalsteinsson et al '878 disclose a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directly onto food pellets. *Col. 9, lines 31-39*. This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Appellants coat a carrier material with the entire contents of the harvested eggs. The coated carrier material is distributed into the animal feed. The animal feed mixed with the coated carrier material is supplied to the animals. The carrier material is defined in Claims 15, 18 and 21 as a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

Betz et al '867 disclose a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody.

Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a dry carrier material with IgY antibody as defined in Claims 14, 17 and 20 to dry wet egg contents.

In view of the absence of a teaching of the claimed drying of antibody yolk and albumin

with a dry carrier material by *Betz et al* '867 and *Adalsteinsson et al* '878, it would not have been obvious to a person skilled in the art to make and use the method claimed in Claims 9-10, 12-13 and 15-16.

It would not have been obvious to one skilled in the art to develop a method for making a microbial adherence inhibitor including the step of providing a dry carrier material and coating the dry carrier material with the wet separated entire contents of the harvested eggs in view of the teachings of the combined references. Further, the Examiner has completely failed to show any motivation to combine either the *Tokoro* '895 reference or the *Yokoyama et al* reference each with the six secondary references. There is certainly no "clear and particular" showing of motivation to combine the multitude of references based on objective evidence of record.

Appellants request that this rejection be reversed.

G. Claims 20-28 and 38 are rejected under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) or *Yokoyama et al* (*Infection and Immunity*, 60(3): 998-1007, March 1992) each in view of *Kaspers et al* (*Zentralbl Veterinarmed*, A43(4): 225-231, June 1996), U.S. Patent No. 5,471,489 (*Pimental*), *Trinchieri et al* (*Urol Res*, 18(5): 305-308, 1990), U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 4,166,867 (*Betz et al*), U.S. Patent No. 4,748,108 (*Stolle et al*), and *Sugita-Konishi et al* (*Biosci Biotechnol Biochem*, 60(5): 886-888 (May 1996).

Claims 20, 23 and 26 define a method for the production of a microbial adherence inhibitor by inhibiting the adherence of colony-forming immunogens. The entire contents of eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins are administered to the animals to promote the growth of the animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the protein-wasting immunogens which inhibits the ability of the protein-wasting immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. The protein-wasting immunogens are identified as *Listeria* antigen from *Listeria*, *Salmonella* antigen from

Salmonella and *Campylobacter* antigen from *Campylobacter*.

Claims 21-22, 24-25, 27-28 and 38 include the step of providing a dry carrier material and coating the dry feed carrier material with the wet separated entire contents of the harvested eggs to dry the eggs. The entire contents of the separated eggs are not dried before coating the dry carrier material with said contents of the eggs.

Appellants' analysis, *supra*, concerning the primary references, *Tokoro '895* and *Yokoyama et al*, and secondary references, *Kaspers et al*, *Pimental '489*, *Trinchieri et al*, *Stolle et al '018*, *Adalsteinsson et al '878*, *Betz et al '867* and *Sugita-Konishi et al*, are applicable to this rejection of Claims 20-28 and 38.

The inclusion of a dry carrier material and coating the material with the wet entire contents of harvested eggs is not shown or suggested by the prior art, either alone or in combination. Further, there is no "clear and particular" objective evidence of record showing motivation to combine the myriad references. The Examiner has again completely failed to show any motivation to combine his references.

Appellants request that this rejection be reversed.

H. Claims 1, 3 and 5-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 14-16, 19-24, 27-32 of co-pending Application Serial No. 09/616,843.

The present application is a division of parent U.S. Application Serial No. 09/616,843 pending before the Board of Appeals and Interferences. No claims have been allowed. Claims 14-16, 19-24 and 27-32 of Application Serial No. 09/616,843 define a method of promoting the growth of food animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogen in the rumen or intestinal tracts of food animals and reducing the ability of the immunogen to multiply.

The Examiner in Application Serial No. 09/616,843 made the following restriction

requirement under 35 USC 121.

"Restriction to one of the following inventions is required under 35 U.S.C 121:

- I. Claims 1-3, method for the production of a microbial adherence inhibitor in the form of egg antibody to food animal, classified in Class 424, subclass 131.1.
- II. Claims 4-9, drawn to drawn to colony-forming immunogen, and microbial adherence inhibitor in the form of fowl egg antibody to food animal, classified in Class 530, subclass 387.1.
- III. Claims 10-11, drawn to method of promoting the growth of food animals by inhibiting the ability of the colony-forming protein-wasting immunogen to the rumen of food animals, classified in Class 424, subclass 826.
- IV. Claims 12-13, drawn to method of reducing or eliminating the incidence of illnesses caused by the presence of targeted colony-forming illness-causing immunogen in meat by inhibiting the immunogen to adhere to the rumen of food animals, classified in Class 424, subclass 826."

The claims in the present application are Group I invention drawn to a method for the production of a microbial adherence inhibitor.

Claims 14-16, 19-24 and 27-32 of Application Serial No. 09/616,843 are the Group III invention.

In view of the restriction requirement of Application Serial No. 09/616,843 and the Group I invention claims of the present application, it is requested that the double patenting rejection of Claims 1, 3 and 5-38 be reversed.

I. Claims 5 and 17-28 are provisionally rejected under the judicially created doctrine of obviousness double patenting as being unpatentable over Claims 1-18 of co-pending Application Serial No. 10/039,977.

Application Serial No. 10/039,977, a division of U.S. Application Serial No. 09/916,843, has been abandoned. No claims have been allowed. Claims 1-18 of Application Serial No. 10/039,977 define a method of reducing or eliminating the incidence of illnesses in humans caused by the presence of colony-forming bacteria of the class comprising *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. These claims are Group IV claims of the restriction requirement

of parent Application Serial No. 09/616,843. Application Serial No. 11/085,674, a continuation of Application Serial No. 10/039,977, is pending.

Appellants submit that this rejection of Claims 5 and 17-28 be reversed in view of the restriction requirement in parent Application Serial No. 09/616,843 and the abandonment Application Serial No. 10/039,977.

The reversal of the Examiner's rejections of Claims 1, 3 and 5-38 is requested.

Respectfully submitted,

PETER NASH ET AL

By

Richard O. Bartz
Registration No. 20,468
6750 France Avenue South, Suite 350
Edina, MN 55435-1983
(952) 920-3959



CLAIMS APPENDIX

1. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals, which method comprises:
 - A. Inoculating female chickens, in or about to reach their egg laying age, with a particular targeted colony-forming immunogen;
 - B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the target colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
 - C. Harvesting the eggs laid by the chickens;
 - D. Separating the entire contents of said harvested eggs from the shells; and
 - E. Drying said separated entire contents of said eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the targeted colony-forming immunogen to adhere to the rumen or intestinal tracts of the animals.
3. The method according to Claim 1 wherein: said targeted colony-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilum*.
5. A method for the production of a microbial adherence inhibitor for administration to a living being to inhibit the adherence of a colony forming immunogen in the digestive tract of

the living being, said colony-forming immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*, which method comprises:

- A. Inoculating female chickens in or about to reach their egg laying age with the colony-forming immunogen;
- B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
- C. Harvesting the eggs laid by the chickens;
- D. Separating the entire contents of said harvested eggs from the egg shells; and
- E. Drying said separated entire contents of said eggs, said dried entire contents of said eggs when administered to the living being inhibiting the adherence of the colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

6. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals produced by the method of:

- A. Inoculating female chickens, in or about to reach their egg laying age, with a particular target colony-forming immunogen;
- B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the target colony-forming immunogen, said antibody in the eggs

including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

- C. Harvesting the eggs laid by the chickens;
- D. Separating the entire contents of said harvested eggs from the egg shells;
- E. Providing a dry feed carrier material; and
- F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

7. The method of Claim 6 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

8. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of said food animals, said immunogen is P antigen from *P. anaerobius*, which method comprises:

- A. Inoculating female birds, in or about to reach their egg laying age, with P antigen from *P. anaerobius*;
- B. Allowing a period of time to permit the production in the birds and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including

IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

and

E. Drying said entire contents of said separated eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen of intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

9. The method of Claim 8 including: providing a dry carrier material, said drying of the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

10. The method of Claim 9 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

11. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of said food animals, said immunogen is CS antigen from *C. sticklandii*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C. sticklandii*;

B. Allowing a period of time to permit the production in the birds and eggs laid by the birds of antibody to CS antigen from *C. sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;
and

E. Drying said entire contents of said separated eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

12. The method of Claim 11 including: providing a dry carrier material, said drying of the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

13. The method of Claim 12 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

14. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of said food animals, said immunogen is CA antigen from *C. aminophilum*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C. aminophilum*;

B. Allowing a period of time to permit the production in the birds and eggs laid by the birds of antibody to CA antigen from *C. aminophilum*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;
and

E. Drying said entire contents of said separated eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

15. The method of Claim 14 including: providing a dry carrier material, said drying of the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

16. The method of Claim 15 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

17. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of said food animals, said immunogen is *E. coli* antigen from *E. coli*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with the *E. coli* colony-forming immunogen;

B. Allowing a period of time to permit the production in the birds of antibody to the *E. coli* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;
and

E. Drying said separated entire contents of said separated eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY

immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

18. The method of Claim 17 including: providing a dry carrier material, said drying of the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

19. The method of Claim 18 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

20. (Previously Presented) A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of said food animals, said immunogen is *Listeria* antigen from *Listeria*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with the *Listeria* colony-forming immunogen;

B. Allowing a period of time to permit the production in the birds of antibody to the *Listeria* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;

and

E. Drying the entire contents of said separated eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the

food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

21. The method of Claim 20 including: providing a dry carrier material, said drying of the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

22. The method of Claim 21 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

23. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of said food animals, said immunogen is *Salmonella* antigen from *Salmonella*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with the *Salmonella* colony-forming immunogen;

B. Allowing a period of time to permit the production in the birds of antibody to the *Salmonella* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;
and

E. Drying the entire contents of said separated eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

24. The method of Claim 23 including: providing a dry carrier material, said drying of the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

25. The method of Claim 24 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

26. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a colony-forming immunogen in the rumen or intestinal tracts of said food animals, said immunogen is *Campylobacter* antigen from *Campylobacter*, said method comprising:

A. Inoculating female birds, in or about to reach their egg laying age, with the *Campylobacter* colony-forming immunogen;

B. Allowing a period of time to permit the production in the birds and eggs of antibody to the *Campylobacter* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said harvested eggs from the egg shells;
and

E. Drying the entire contents of said separated eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

27. The method of Claim 26 including: providing a dry carrier material, said drying of the separated entire contents of said eggs is achieved by coating the dry carrier material with the separated entire contents of said eggs.

28. The method of Claim 27 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

29. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the adherence of a targeted colony-forming immunogen in the rumen or intestinal tracts of said food animals, which method comprises:

A. Inoculating female birds, in or about to reach their egg laying age, with the particular targeted colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks in the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the birds;

D. Separating the entire contents of said eggs from the egg shells;

E. Providing a dry carrier material; and

F. Coating said dry carrier material with the entire contents of said eggs, said dried entire contents of said eggs when administered to food animals with animal feed promoting the growth of the food animals by decreasing the waste of dietary protein caused by the presence of a protein-wasting immunogen in the rumen or intestinal tracts of the food animals by binding the IgY immunoglobulins to the protein-wasting immunogen, said binding of the IgY immunoglobulins to the protein-wasting immunogen being assisted by the IgM and IgA immunoglobulins to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of the animals.

30. The method of Claim 29 wherein: the dry carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

31. The method of Claim 29 wherein: said target-forming immunogen is from the class consisting of *P. anaerobius*, *C. sticklandii* and *C. aminophilum*.

32. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is P antigen from *P. anaerobius*, which method comprises:

- A. Inoculating female birds, in or about to reach their egg laying age, with P antigen with *P. anaerobius*;
- B. Allowing a period of time sufficient to permit the production of the bird and eggs laid by the birds of antibody to P antigen from *P. anaerobius*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
- C. Harvesting the eggs laid by the birds;
- D. Separating the entire contents of said harvested eggs from the egg shells;
- E. Providing a dry feed carrier material; and
- F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

33. The microbial adherence inhibitor according to Claim 32 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

34. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CS antigen from *C. sticklandii* produced by the method of:

- A. Inoculating female birds, in or about to reach their egg laying age, with CS antigen from *C. sticklandii*;
- B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to CS antigen from *C. sticklandii*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
- C. Harvesting the eggs laid by the birds;
- D. Separating the entire contents of said harvested eggs from the egg shells;
- E. Providing a dry feed carrier material; and
- F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to

the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

35. The microbial adherence inhibitor according to Claim 34 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

36. A method for the production of a microbial adherence inhibitor for administration to food animals to inhibit the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply, said protein-wasting immunogen is CA antigen from *C. aminophilium* produced by the method of:

- A. Inoculating female birds, in or about to reach their egg laying age, with CA antigen from *C. aminophilium*;
- B. Allowing a period of time sufficient to permit the production in the bird and eggs laid by the birds of antibody to CA antigen from *C. aminophilium*, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;
- C. Harvesting the eggs laid by the birds;
- D. Separating the entire contents of said harvested eggs from the egg shells;
- E. Providing a dry feed carrier material; and
- F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs, said dry food carrier material coated with the entire contents of said eggs when administered to the food animals inhibiting the adherence of

colony-forming immunogen in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

37. The microbial adherence inhibitor according to Claim 36 wherein: the dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

38. A method for the production of a microbial adherence inhibitor for administration to a living being to inhibit the adherence of a colony forming immunogen in the digestive tract of the living being, said colony-forming immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*, which method comprises:

A. Inoculating female chickens in or about to reach their egg laying age with the colony-forming immunogen;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the colony-forming immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the egg shells; and

E. Providing a dry carrier material; and

F. Coating said dry carrier material with the separated entire contents of said harvested eggs, said dry carrier material coated with the entire contents of said eggs when administered to the living being inhibiting the adherence of colony-forming immunogen

in the digestive tract by binding the IgY immunoglobulins to the colony-forming immunogen, said binding of the IgY immunoglobulins to the colony-forming immunogen being assisted by the IgM and IgA immunoglobulins.

RELATED APPLICATIONS APPENDIX

U.S. Application Serial No. 09/616,843 and U.S. Application Serial No.
10/025,567 are pending before the Board of Appeals and Interferences.

EVIDENCE APPENDIX

Office action dated November 9, 2000 in Application Serial No. 09/616,843 filed
July 14, 2000, Paper No. 2, Restriction Requirement.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/616,843	07/14/00	NASH	P C150.12.3B

L PAUL BURD
1300 FOSHAY TOWER
MINNEAPOLIS MN 55402

HM12/1109

Burd, Bartz & Gutenkauf

NOV 20 2000

Received

EXAMINER

HUYNH, P

ART UNIT	PAPER NUMBER
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1644

2

DATE MAILED:

11/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/616,843

Applicant(s)

NASH ET AL.

Examiner

"Neon" Phuong Huynh

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1644

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
2. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, method for the production of a microbial adherence inhibitor in the form of fowl egg antibody to food animal, classified in Class 424, subclass 131.1.
 - II. Claims 4-9, drawn to drawn to colony-forming immunogen, and microbial adherence inhibitor in the form of fowl egg antibody to food animal, classified in Class 530, subclass 387.1.
 - III. Claims 10-11, drawn to method of promoting the growth of food animals by inhibiting the ability of the colony-forming protein-wasting immunogen to the rumen of food animals, classified in Class 424, subclass 826.
 - IV. Claims 12-13, drawn to method of reducing or eliminating the incidence of illnesses caused by the presence of targeted colony-forming illness-causing immunogen in meat by inhibiting the immunogen to adhere to the rumen of food animals, classified in Class 424, subclass 826.

Art Unit: 1644

The inventions are distinct, each from the other because of the following reasons:

A. Groups II and I/III/IV (antibody and process of using antibody) are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, the antibody of Group II can be used as the therapeutic methods as claimed as well as diagnostic/screening, affinity purification assays. Therefore, they are patentably distinct.

B. Groups (I, III and IV) are different methods.

The inventions required different ingredients, process steps and endpoints.

In the instant case, the method of making an antibody to a specific immunogen and the method of using the antibody to vaccinate the food animal. Therefore, they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the search have acquired a separate status in the art as shown by their different classification that recognized as divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed in Groups I and III: wherein the protein-wasting immunogen is:

- A) *P. anaerobius*,
- B) *C. Sticklandii*, or
- C) *C. aminophilum*.

And the following patentably distinct species of the claimed Groups I and IV wherein the illness-causing immunogen is:

- A) *E. coli*,
- B) *Listeria*,
- C) *Salmonella* or
- D) *Campylobacter*.

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The methods of treating food animals with different immunogen differ with respect to their structure, and mode of action for the different microorganisms. Therefore they are patentably distinct.

6. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 11 and 13 are generic.
7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
11. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Art unit 1644
Technology Center 1600
November 6, 2000

PHILLIP GAMBEL
PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
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